

### **REMARKS**

Claims 13-19 and 28-53 are currently pending.

### **CLAIM REJECTION**

#### ***Rejection of claims under 35 U.S.C. § 112, first paragraph***

The Examiner has maintained the rejection of claims 13-19 and 28-53 under 35 U.S.C. § 112, first paragraph, "because the specification, while being enabling for hexose oxidase, does not reasonably provide enablement for all oxidoreductases." See Office Action at p. 2. The Examiner contends that the Declaration filed on May 30, 2008 "presented to show that the disclosure of an application is sufficient to one skilled in the art [is] not acceptable to establish facts which the specification itself should recite." See Office Action at p. 3. The Examiner cites *In re Buchner*, 929 F.2d 660, 18 USPQ2d 1131 (Fed. Cir. 1991) to support this contention. *Id.* The Examiner further argues that only hexose oxidase as an oxidoreductase is contemplated in the specification and that no other oxidoreductases are taught. See Office Action at p. 2. Applicants respectfully disagree with this contention and traverse this rejection.

The actual statement in *In re Buchner* decision states that "§112 requires that, **unless the information is well known in the art**, the application itself must contain this information; it is not sufficient to provide it only through an expert's declaration." (emphasis added by Applicants). *Id.* at 1332. As to the information known to one of skill in the art at the time of filing, the MPEP provides that "Applicant may submit factual affidavits under 37 CFR 1.132 or cite references to show what one skilled in the art knew at the time of filing the application." See MPEP 2164.05. The MPEP further states that

A declaration or affidavit is, itself, evidence that must be considered. The weight to give a declaration or affidavit will depend upon the amount of factual evidence the declaration or affidavit contains to support the conclusion of enablement. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991) ("expert's opinion on the ultimate legal conclusion must be supported by something more than a conclusory statement"); ....

(original emphasis). To further distinguish the present application from the *In re Buchner* case, *In re Buchner* involved a declaration from an expert who concluded that the design structures of two elements "well known to those of ordinary skill in the art." See 18 USPQ2d 1332. The

court found that “[h]e did not provide adequate support for his conclusion” and that “he did not demonstrate that such construction was well-known to those of ordinary skill in the art.” *Id.*

In contrast, Applicants in the Declaration filed on May 30, 2008 provide additional evidence demonstrating glucooligosaccharide oxidase (an oxidoreductase) was known in the art at the time of filing and known to be capable of oxidizing maltose (See Lin *et al.*, “Purification and characterization of a novel glucooligosaccharide oxidase from *Acremonium strictum* T1,” *Biochemica et Biophysica Acta*, Vol. 1118, p. 41-47 (1991) (“Lin *et al.*”). The Lin *et al.* reference provides an example of an oxidoreductase which is able to oxidize maltose that has beneficial effects on rheological properties of a dough. The Lin *et al.* reference and other references were submitted in a response to an Office Action filed April 2, 2003 in the parent application U.S. Serial No. 09/932,923 (now U.S. Patent No. 6,726,942) as examples of references which disclose or suggest other oxidoreductases capable of oxidizing maltose at the priority date of the application. Accordingly, Applicants respectfully submit that since the information is well known in the art (i.e. other oxidoreductases capable of oxidizing maltose), Applicants do not have to list each and every single oxidoreductase capable of oxidizing maltose in the specification.

The Declaration further demonstrates that glucooligosaccharide oxidase is able to oxidize maltose. See Table 1 and paragraph 6 of the Declaration. The Declaration also demonstrates that glucooligosaccharide oxidase results in the oxidation of free thiol in wheat gluten of dough slurry. See Figures 2 and 3 and paragraphs 7-8 of the Declaration. This oxidation by glucooligosaccharide oxidase is shown by a decrease in the amount of free thiol in the dough slurry when compared to the sample with the inactivated enzyme. Such an oxidation of free thiol groups on gluten molecules result in the formation of disulphide bridges in the gluten network which thereby improves the rheological properties of the dough as well as improve the dough handling properties and the quality of the baked goods. The Declaration provides additional support that oxidoreductases, other than hexose oxidase, can be used in dough improving compositions and flour doughs of the present application. Thus, Applicants’ recognition that oxidoreductases other than hexose oxidase, can be used in dough improving compositions and flour doughs was part of the original application and adequately disclosed. The Declaration supports this fact.

Applicants further emphasize that Applicants are “are **not** required to disclose every species encompassed by their claims even in an unpredictable art” (original emphasis). *In re Angstadt*, 537 F.2d 498, 503 (CCPA 1976). As such, Applicants are not required to disclose every single oxidoreductase capable of oxidizing maltose. All the law requires is that the Applicants provide a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of the claims. The specification has informed and demonstrated to a person having ordinary skill in the art how to use the invention commensurate in scope with the claims. The specification teaches the use of any oxidoreductase capable of oxidizing maltose, for instance, p. 5, lines 16-18 and p. 8, lines 21-22, make it clear that hexose oxidase is one type of oxidoreductase capable of oxidizing maltose of use in one embodiment of the invention. The specification *per se* does **not** limit the oxidoreductase capable of oxidizing maltose to being just hexose oxidase.

As such, Applicants request that the Examiner “weigh all the evidence before ... her, including the specification and any new evidence supplied by the applicant with the evidence and/or sound scientific reasoning previously presented in the rejection and decide whether the claimed invention is enabled.” See MPEP 2164.05. Applicants believe that Applicants have informed and demonstrated to a person having ordinary skill in the art how to use the invention commensurate in scope with the claims. Applicants respectfully request reconsideration and withdrawal of this rejection with respect to claims 13-19 and 28-53.

### ***Rejection of claims under 35 U.S.C. § 102***

The Examiner has rejected claims 13, 17, 18, 28, 32, 33, 35-40, 44-48 and 52 under 35 U.S.C. § 102(b) as being anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,451,413 to Fok et al. (“Fok”). See Office Action at p. 3. Claims 17 and 18 depend from independent claim 13. Claims 32-33 depend from independent claim 28. Claim 35 is an independent claim. Claims 37-40 depend from independent claim 36. Claims 45-48 and 52 depend from independent claim 44.

Applicants have discovered a dough improving composition including an oxidoreductase which is at least capable of oxidizing maltose and at least one further dough ingredient or dough additive. Applicants have also discovered a dough improving composition including an

oxidoreductase which is at least capable of oxidizing maltose, flour and at least one further dough ingredient or dough additive wherein the oxidoreductase is in an amount which results in the presence in a finished dough of 1 to 10,000 units per kg of flour.

Applicants have further discovered a dough including a dough improving composition including an oxidoreductase which is at least capable of oxidizing maltose and at least one further dough ingredient or dough additive, and flour. Applicants have discovered a flour dough including an oxidoreductase which is at least capable of oxidizing maltose and flour. Applicants have also discovered a baked or dried product produced from a flour dough wherein the flour dough includes an oxidoreductase which is at least capable of oxidizing maltose. A key technical aspect of the present invention is the recognition for the first time that maltose in a dough environment could be oxidized by an oxidoreductase enzyme to yield beneficial results. By utilizing the maltose in the dough, the dough improving composition of the present invention surprisingly results in desirable improvements in doughs. Namely, the composition improves the quality of dough and the finished products of dough – in particular, it improves the rheological properties, extensibility, stability, volume and strength (see for example, p. 5, lines 16-29, p. 7, lines 17-21, p. 12, line 32 to p. 15, line 2, paragraphs spanning pp. 15 and 16, Example 2.4, Example 3, Example 4 and Example 5 of the specification). When an oxidoreductase oxidizes maltose,  $H_2O_2$  is released which oxidizes free thiol groups on gluten molecules in the dough. This results in the formation of disulphide bridges in the gluten network, resulting in a dough with better rheological properties. See, for example, Example 2.4 of the specification.

In contrast, Fok describes “a method for improving the rheological properties of dough and quality of baked products by addition of a yeast derivative, preferably in combination with a reducing agent and/or enzyme preparations having amylase, hemicellulase, oxido reductase and/or protease activities.” See Abstract. Fok further describes that a preferred reducing agent is L-cysteine. See col. 2, line 30 of Fok. The enzymes which are use in the examples in Fok are amylase, glucose oxidase and protease. Additionally, Fok states that the preferred oxidoreductase is glucose oxidase. See col. 2, line 32 of Fok. Moreover, the only oxidoreductase which is used in the examples of Fok is glucose oxidase. No other oxidoreductases are mentioned in Fok.



The present application makes it clear that glucose oxidase is not an enzyme capable of oxidizing maltose. See p. 5, line 30 to p. 6, line 7 of the specification. For avoidance of doubt, an oxidoreductase capable of oxidizing maltose (i.e. a MOX) is not a glucose oxidoreductase (i.e. a GOX). GOX is a *completely different enzyme* which acts on a *completely different substrate*. In connection to this, Applicants enclose an extract from the Enzyme Nomenclature Book, attached at Exhibit A. Glucose oxidase has the EC number 1.1.3.4 and it acts on the substrate glucose – it does not act on other substrates. In contrast, hexose oxidase has the EC number 1.1.3.5 and it is capable of oxidizing glucose, maltose, D-galactose, D-mannose, lactose and cellobiose. See Exhibit A.

Applicants further enclose a copy of Garcia et al., *J Agric Food Chem*, Vol. 52, p. 3946-3953 (2004) at Exhibit B. This reference was published after the filing date of the present invention. The second paragraph on p. 3946 states that GOX catalyzes the oxidation of glucose to gluconolactone. Further, the paragraph spanning p. 3946 confirms that HOX, *unlike GOX*, uses several monosaccharides and oligosaccharides as substrates and catalyzes the conversion into lactones with the formation of hydrogen peroxide. Moreover, this paragraph concludes with “HOX caused dough strength and increased bread volume more efficiently than GOX in the same dosage” – highlighting another surprising advantage in using an oxidoreductase capable of oxidizing maltose rather than a glucose oxidoreductase.

Therefore, Fok does not describe a dough improving composition or a flour dough including an oxidoreductase which is at least capable of oxidizing maltose as described in independent claims 13, 28, 35, 36 and 44. As such, claims 13, 17, 18, 28, 32, 33, 35-40, 44-48 and 52 are not anticipated by Fok. Applicants respectfully request reconsideration and the withdrawal of this rejection.

### ***Rejection of claims under 35 U.S.C. § 103***

The Examiner has rejected claims 13, 17, 18, 28, 32, 33, 35-40, 44-48 and 52 in the alternative, under 35 U.S.C. § 103(a) as being obvious over Fok. See Office Action at p. 3. The Examiner has further rejected claims 14-16, 19, 29-31, 34, 41-43, 49-51 and 53 under 35 U.S.C. § 103(a) as being unpatentable over Fok. See Office Action at p. 4. Claims 14-19 depend from independent claim 13. Claims 29-34 depend from independent claim 28. Claim 35 is an

independent claim. Claims 37-43 depend from independent claim 36. Claims 45-53 depend from independent claim 44.

As previously explained, Fok does not describe a dough improving composition or a flour dough including an oxidoreductase which is at least capable of oxidizing maltose as described in independent claims 13, 28, 35, 36 and 44. Fok further does not teach or suggest a dough improving composition or a flour dough including an oxidoreductase which is at least capable of oxidizing maltose as described in independent claims 13, 28, 35, 36 and 44.

While Fok states that the preferred oxidoreductase is glucose oxidase (see col. 2, line 32 of Fok), there is no motivation in Fok to use oxidoreductase glucose oxidase over and above any of the other reducing agents or enzyme preparations mentioned therein. Further, there is no teaching in Fok which would motivate a person of skill in the art to depart from the use of the specific oxidoreductase glucose oxidase taught therein. To assert otherwise would involve hindsight. Finally, as explained above, the difference between the present invention and Fok is that the oxidoreductase in the dough improving composition is an oxidoreductase capable of oxidizing maltose. Until the present invention, no one had considered *maltose* as being a suitable or even beneficial enzymatic target for oxidation in dough processing.

In connection to this, Applicants enclose a copy of Chapter 2.5 of Industrial Enzymology (attached as Exhibit C) which focuses on baking. This textbook was published *after* the priority date of the present invention and provides a good picture of the state of mind of the skilled person at the priority date of the present invention. The Table on p. 99 summarizes the enzymes such as amylases (which hydrolyze starches to maltose) and glucose oxidase. Page 100 details potential new enzymes for use in baking. Such enzymes include glucose oxidase.

Other references published before or around the priority date of this invention teach a person of skill in the art to increase the levels of maltose in a dough and not to *decrease* the level as would occur when using an enzyme capable of oxidizing maltose. Applicants provide as an example, EP 0 468 731 and EP 0 338 452 (attached as Exhibit D and E respectively). EP 0 468 731 discloses that it is important to use amylases with glucose oxidase as the amylase hydrolyzes starches to maltose and this enzymatic product provides extensibility to the dough, improves oven spring and keeps the quality of the dough. See p. 1, lines 41-44 and p. 3, lines -8 of EP 0 468 731. Further EP 0 338 452 mentions that an increased formation of maltose improves the

crust color, aroma and taste of the final product. See p. 2, lines 39-41 of EP 0 338 452. Both references teach the skilled person to *increase* maltose levels and not degrade maltose. Hence a person of skill in the art would have readily considered that it was *important not* to reduce the level of maltose in the dough. In other words, there were clear disincentives in the art to use any other oxidoreductase other than glucose oxidase.

As such, there is no motivation to modify the teachings of Fok to arrive at the present invention. Fok further does not teach or suggest a dough improving composition or a flour dough including an oxidoreductase which is at least capable of oxidizing maltose as described in independent claims 13, 28, 35, 36 and 44.

Accordingly, claims 13, 28, 35, 36 and 44, and claims that depend therefrom are patentable over Fok. Applicants respectfully request that this rejection be reconsidered and withdrawn.


### **CONCLUSION**

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the pending rejections. Applicants believe that the claims now pending are in condition for allowance.

Should any fees be required by the present Amendment, the Commissioner is hereby authorized to charge Deposit Account **19-4293**.

Respectfully submitted,

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